



Wyeth Pharmaceuticals
206 N Biddle Street
Marietta, PA 17547

Dennis J. Foley, Ph.D.
Assistant Vice President
Worldwide Regulatory Affairs

November 26, 2003

Mr. John Becher
Centers for Disease Control/Drug Service, D-09
1600 Clifton Road
Atlanta, GA 30333

**Re: STN 101106/5041 – Smallpox Vaccine Dryvax[®]
Extension of Dating**

Dear Mr. Becher:

Please note that Wyeth received approval on November 25, 2003 for BLA supplement 101106/5041 to extend dating from 12 to 18 months for the following lots of Smallpox Vaccine Dryvax[®] kits:

<u>Lot Number</u>	<u>New Expiration Date</u>
4020077	May 2004
4020076	May 2004
4030020	June 2004

Additional testing in accordance with the protocol filed to our license is planned and a CBE supplement will be filed to extend the expiration dating beyond 18 months, if appropriate.

Please note that the storage period of the vaccine after reconstitution with diluent continues to be 90 days.

Sincerely yours,

Dennis J. Foley, Ph.D.

DJF:jm

cc: J. Grabenstein (DOD)
D. Staten (CBER)
D. Yeskey (CDC)